

Claim Listing

Claims 14-16 are pending. Claims 1-13 and 17-33 are canceled. Claims 34-36 are new.

1-13. (Canceled).

14. (Currently amended) A method of performing a clinical trial comprising:
_____ randomizing with a processor study participants into a plurality of treatment
groups;
_____ performing a first phase of testing, said first phase of testing including
administering an active treatment to a first group of said plurality of treatment groups, and
administering a placebo to a remainder of said treatment groups;
_____ determining whether each participant in each of said treatment groups is a
responder or a non-responder;
_____ performing a second phase of testing, said second phase of testing including
administering said placebo to at least one non-responder in at least one group, and administering
said active treatment to at least one non-responder in at least one group; and
_____ analyzing with a processor data from said first phase of testing and from said
second phase of testing.
_____ wherein said analyzing comprises determining an effect of active treatment, and
~~The method of claim 11~~ wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$$
 wherein h is ~~the~~ a value representative of effectiveness of the active treatment, w is a weighting factor, p₁ is ~~the~~ a response rate to the first administration of active treatment during said first phase, q₁ is ~~the~~ a response rate to the first administration of placebo during said first phase, p₂ is ~~the~~ a response rate to the second administration of active treatment during said second phase, and q₂ is ~~the~~ a response rate to the second administration of placebo during said second phase.

15. (Currently amended) A method of performing a clinical trial comprising:
_____ randomizing with a processor study participants into a plurality of treatment
groups;

_____ performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups, and administering a placebo to a remainder of said treatment groups;

_____ determining whether each participant in each of said treatment groups is a responder or a non-responder;

_____ performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group; and

_____ analyzing with a processor data from said first phase of testing and from said second phase of testing.

_____ wherein said analyzing comprises determining an effect of active treatment, and

~~The method of claim 11~~ wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w \left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3} + n_{2,3})}{2na} \right) + (1 - w) \left(\frac{n_{2,1}}{n_{2,1} + n_{2,2}} - \frac{n_{1,1}}{n_{1,1} + n_{1,2}} \right),$$

wherein ~~h is the~~ a value representative of effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, ~~n is the total number of study participants~~, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, ~~[[n_{3,1}]]~~ $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

16. (Original) The method of claim 14 wherein data from said administering placebo to non-responders in said first group is not used in said determining said placebo response rate

17-33. (Canceled).

34. (New) A method of performing a clinical trial comprising:
performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study participants, and administering a placebo to a remainder of said plurality of treatment groups of study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;
determining whether each participant in each of said treatment groups is a responder or a non-responder; and
performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,
wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,
wherein said analyzing comprises determining an effect of active treatment, and
wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$$
, where h is a value representative of effectiveness of the active treatment, w is a weighting factor, p_1 is a response rate to the administration of active treatment during said first phase, q_1 is a response rate to the administration of placebo during said first phase, p_2 is a response rate to the administration of active treatment during said second phase, and q_2 is a response rate to the administration of placebo during said second phase.

35. (New) A method of performing a clinical trial comprising:
performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study

participants, and administering a placebo to a remainder of said plurality of treatment groups of study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder; and

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,

wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w \left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3} + n_{2,3})}{2na} \right) + (1 - w) \left(\frac{n_{2,1}}{n_{2,1} + n_{2,2}} - \frac{n_{1,1}}{n_{1,1} + n_{1,2}} \right),$$
 where h is a value representative of

effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

36. (New) The method of claim 34 wherein data from said administering placebo to non-responders in said first group is not used in said determining said placebo response rate.